Proposed Maximum Residue Limit PMRL2013-03

Spinetoram

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has granted full registration to technical grade spinetoram and the end-use products Radiant SC and Delegate WG for use in Canada on various commodities. Details regarding these applications can be found in Proposed Registration Decision PRD2012-31, *Spinetoram*, posted to the Health Canada website on December 21, 2012.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

In addition, the PMRA is proposing to revise the MRL for spinetoram on citrus oil to permit its import and sale. The PMRA has determined that the quantity of residues likely to remain in or on imported citrus oil when spinetoram is used according to label directions in the exporting country, and that such residues will not be a concern to human health. Details regarding the proposed MRL on imported citrus oil can also be found in PRD2012-31.

Consultation on the proposed MRLs for spinetoram was conducted via PRD2012-31. Information regarding the proposed MRLs can be found in Section 3.5.4. Supporting processing study data are provided in Appendix 1, Table 4. The PMRA received no comments in response to this consultation.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace MRLs already established for spinetoram, are as follows.

Table 1 Proposed Maximum Residue Limits for Spinetoram

Common Name	Residue Definition	MRL (ppm)	Food Commodity
Spinetoram	XDE-175-J: 1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-a-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino) tetrahydro-6-methyl 2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10,11,12,13,14,16a, 16b-hexadecahydro 14-methyl-(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*, 16a*S*,16b*R*) XDE-175-L: 1*H*-as-indaceno[3,2-*d*]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-a-L-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino) tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a, 16b-tetradecahydro-4,14-dimethyl-(2*S*,3a*R*, 5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*) including the metabolites: N-demethyl-175 J: (2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-9-ethyl-14-methyl-13-{[(2*S*,5*S*,6*R*)-6-methyl-5-(methylamino) tetrahydro-2*H*-pyran-2-yl]oxy}-7,15-dioxo-2,3,3a,4,5, 5a,5b,6,7,9,10,11,12,13,14,15, 16a,16b-octadecahydro-1*H*-as-indaceno[3,2-d] oxacyclododecin-2-yl 6-deoxy-3-*O*-ethyl-2,4-di-*O*-methylalpha-L-mannopyranoside N-formyl-175-J: (2*R*,3*S*,6*S*)-6-({(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-3-*O*-ethyl-2,4-di-*O*-methyl-alpha-L-manno pyranosyl)oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16boctadecahydro-1*H*-as-indaceno[3,2-d]oxacyclododecin-13-yl}oxy)-2-methyltetrahydro-2*H*-pyran-3-yl(methyl)formamide	9.0[a] 0.5[b]	Citrus oil Small fruits vine climbing subgroup except fuzzy kiwifruits (Crop Subgroup 13-07F; except gooseberries)

ppm = parts per million

[a] The MRL is proposed to replace the currently established MRL of 3.0 ppm for citrus oil.

[b] The MRL is proposed to replace the currently established MRL of 0.4 ppm for CSG 13-07F. The current established MRLs of 0.7 ppm for raisins, and 1.0 ppm for grape juice are proposed to be revoked as residues of spinetoram will be covered by the proposed MRL for CSG 13-07F (except gooseberries).

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 2 compares the MRLs proposed for spinetoram in Canada with corresponding American tolerances and Codex MRLs[1]. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL[a] (ppm)	American Tolerance[a] (ppm)	Codex MRL[b] (ppm)
Citrus oil	9.0	3.0	Not Established
Raisins	0.5[c]	0.7	Not Established
Small fruits vine climbing subgroup except fuzzy kiwifruits (crop subgroup 13-07F; except gooseberries)	0.5	0.5 (Grape)	Not Established

[a] Residue definition for enforcement: Spinetoram (XDE-175-J, XDE-175-L), and the metabolites N-demethyl-175-J (ND-J), and N-formyl-175-J (NF-J)

[b] Residue definition for enforcement: Spinetoram (XDE-175-J, XDE-175-L)

[c] No separate MRL is established for raisins. Residues are covered by the proposed MRL for CSG 13-07F (except gooseberries).

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for spinetoram up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.